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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SITTON, JEHANNE SOUAYA	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/758,987	BEUCKELEER, MARC DE	
	Examiner	Art Unit	
	Jehanne Souaya Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-31 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-31 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 28-31 and 34 are pending in the instant application. Claims 32 and 33 are canceled. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The rejection of claim 28 under 35 USC 102(b) and claim 31 under 35 USC 102(a) are withdrawn in view of the amendment to claim 28. The following rejections are newly applied but contain grounds of rejection maintained from the previous office action. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is NON-Final.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Grounds of Rejection

Written Description

3. Claims 28-31 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to DNA molecules that result from amplification using primers. With regard to claims 28, 31 and 34, one primer consists a sequence of 15-30

nucleotides that is complementary to specific nucleotide positions within SEQ ID NO: 6 or SEQ ID NO: 10 and a second primer consists of a sequence of 15-30 nucleotides that is complementary to specific nucleotide positions within SEQ ID NOS: 1, 6 or 10. It is noted that due to the word "complementary" such primer can contain sequences not fully complementary to the recited portions of SEQ ID NOS 6, 10, or 1. The specification demonstrates at page 11, lines 1-6, that the term 'identity' as well as the term 'complementary' can encompass different degrees of complementarity, including between 80% and 100%. Therefore the claims do not actually limit the primer sequences to any particular nucleic acid sequence. Therefore, the claim is broadly drawn to a nucleic acid that can be amplified by primers with less than 100% complementarity to SEQ ID NO: 1, 6 or 10.

Further, the claims recite: "A DNA molecule, which can be amplified...". The recitation of the word "can" however is unclear if the DNA molecule is produced by, or merely can be amplified by the recited sequences. It is noted that a DNA molecule that is larger than a fragment amplified by the primers "can" be amplified by the specific primers. As such, all the claims read on any nucleic acid molecule having undisclosed sequences on either of the flanking primers, which encompasses nucleic acids of unlimited size which contain undisclosed genomic DNA as well as "foreign DNA". With regard to claims 28-31 and 34, although these claims contain limitations as to primer sequences with specific SEQ ID NOS (29-30) or regions of SEQ ID NOS (28, 31, 34) and specific PCR conditions, such claims still read on a large genus of nucleic acids, including undisclosed genomic DNA, whole genes, and fragments thereof, that have not been taught or described in the specification. The claims are not limited to a specific corn plant (ie: a specific strain), wherein large amounts of variability exist in such plants such

that the genus of nucleic acids encompassed by the claims is extremely large. Further, it is well known that non-specific amplification results from PCR, for example, wherein DNA molecules are amplified that are not completely complementary to the primers used for amplification. The instantly pending claims thus encompass a genus of undisclosed non-specifically amplified DNA sequences as well, which can result from the PCR conditions specified.

Additionally the term "GAT-ZM1" is not described by the specification to be limited to any particular DNA sequence. "GAT-ZM1" appears to refer to the incorporation of a specific vector into the genome of a corn plant which results in a specific set of desired phenotypic qualities. The regions flanking the insertion of the vector have been sequenced (SEQ ID NOS 6 and 10) and contain both foreign DNA and plant DNA. However, the specification defines "foreign DNA" as also encompassing rearranged DNA of the plant (see page 5). The specific DNA sequence of the elite event "GAT-ZM1" has not been defined. From the disclosure in the specification, it appears that the "foreign DNA" flanked by the plant DNA sequences in SEQ ID NOS 6 and 10 contain rearranged plant DNA whose sequence has not been taught by the specification. Further, it is unclear if "GAT-ZM1" refers to only one specific sequence, though even if "GAT-ZM1" were limited to a particular sequence, that sequence has not been taught by the specification. Even if the claims were amended to recite "A DNA molecule which is produced by PCR with a primer pair consisting of SEQ ID NOS 11 and 12" and the claim recited specific PCR conditions, the claims would still only be defined by primers which would flank the ends of the molecule. This is not a description of the molecule itself, but a description of the areas flanking a genus of potential molecules whose sequences have not been taught. Further, while the sequences set forth in the claims could be used to determine the sequences of the

molecules encompassed by the claims, such primers only represent a description of how to find or make the genus of possible DNA molecules that are encompassed by the claims. This is not the same as a description of the DNA itself. The DNA molecules that could be produced by the sequences set forth in the claims represent a genus with substantial variability that is not described by the specification. Additionally, it is known that genetic variability exits in corn plants. Given that the claims don't even set forth a specific corn plant or a specific sample, again, the DNA molecules that could be produced by the sequences set forth in the claims represent a genus with substantial variability which is not described by the specification. Further, only a portion of the plant DNA corresponding to the specific event in the specification, has been described, the plant DNA flanking the event. However, even if the full fragment had been described, plant DNA sequences flanked by the primer molecules could comprise mutants, variants, and homologs of plant DNA in the elite event set forth in the specification. This represents a genus of sequences for which.

Therefore, the claims encompass an extremely large number of DNA molecules, which include genomic DNA, genes, or fragments, from any corn plant, that have not been taught or described in the specification. Neither, the partial plant DNA sequences delineated by SEQ ID NOS 6 and 10, nor the full sequences of SEQ ID NO: 6 or SEQ ID NO: 10 are representative of this extremely large genus of nucleic acids.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NOS: 6 and 10, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Response to Arguments

4. The response traverses the rejection. The response asserts that the statement that "GAT-ZM1 is not limited to a single event in a single strain of corn" made by the examiner in the previous office action is misguided because by its very definition, an elite event is the incorporation of a transgene or "foreign DNA" into one specific locus in the host genome. This argument has been thoroughly reviewed but was found unpersuasive because as set forth above, the locus itself is not fully described. It is unclear as to what specific DNA sequence actually defines the locus. As set forth above, a molecule can be amplified by virtue of the fact that primers within a sequence are used to generate multiple copies of a sequence within the molecule. However, even if the claims were amended to recite a DNA molecule produced by amplification of two specific primers, the sequence of the molecule has not been taught. The primers only serve to define the ends of the sequence, and were they to be removed, the sequence itself, that is the molecules encompassed by the claims, would have no structural relationship to the primers. A large genus of sequences which contains substantial variability is encompassed by the claimed recitation. These sequence can result from non specific amplification, even with the conditions set forth in the claims, as well as due to variability within corn plants. The response sets forth a diagram which is a schematic representation of the event outlined in the specification. However, the actual sequence defining the locus is not provided in the diagram or in the specification. The 'foreign' DNA outlined in the diagram can contain rearranged plant DNA, such that the disclosure of the 'plant DNA' sequences flanking the insertion as well as the vector sequence of SEQ ID NO: 1 is not a complete disclosure of the actual locus defining the elite event 'GAT-ZM1' outlined in the specification. Additionally, given that substantial

variability exists in corn plants, as well as the occurrence of transposable elements and pseudogenes, merely setting forth regions which contain somewhere within them, primer sequences, as well specific primer sequences, is only a description of how to make or find the genus of possible DNA molecules which are encompassed by the claims. This is not a description of the DNA itself.

With regard to nonspecific amplification, the response sets forth that Fig 1 shows that the conditions used in the claims does not generate non specific amplification. This argument has been thoroughly reviewed but was not found persuasive. Firstly, the figure pointed to in the response is a copy of a gel taken from a specific transformation event with a specific samples of corn. Firstly, it is unclear whether or not the resolution of this copy, or the portion of the gel depicted in the figure, would identify any non specifically amplified fragments. Additionally, the figure represents bands on a gel, whose specific sequences are not identified. It cannot be determined from this figure if the sequences of the bands are the same or not.

The response asserts that although the lengths of the fragments of encompassed by the claims may change, the template remains the same. This argument was thoroughly reviewed but was not found persuasive because while the primers themselves are defined, the full template that they are amplifying has not been taught.

Indefinite

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 28-31 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "A DNA molecule, which can be amplified...". The recitation of the word "can" however is indefinite because it is unclear if the DNA molecule is produced by, or merely can be amplified by the recited sequences. It is noted that a DNA molecule that is larger than a fragment amplified by the primers "can" be amplified by the specific primers. However, the response dated January 15, 2004 argues that the claims are limited to specific fragments amplified by the sequences set forth in the claim. Therefore, the metes and bounds of the claimed DNA molecules are unclear. This rejection can be overcome by reciting "A DNA molecule produced by PCR from a nucleic acid sample of corn..."

Conclusion

7. No claims are allowable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

Note: The examiner's name has changed from Jehanne Souaya to Jehanne Sitton. All future correspondence to the examiner should reflect the change in name.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (571) 272-0507.

Jehanne Sitton

Jehanne Sitton
Primary Examiner
Art Unit 1634
3/30/04